Remarks

The Applicants confirm the earlier election of Group I and the earlier election of species. Examination of Claims 1 – 10, 13 – 17 and 23 – 28 is confirmed.

The Applicants note with appreciation the Examiner's helpful comments concerning the use of trademarks. The Applicants have reviewed the Specification and made appropriate changes. Entry into the Official File is respectfully requested.

The Drawings stand objected to because they include reference numbers not mentioned in the Description. The Applicants respectfully submit, however, that the eight reference numbers shown in Fig. 12 are indeed set forth in detail in the Applicants' Specification. In that regard, the Applicants invite the Examiner's attention to page 11 of the Applicants' Specification. All eight reference numbers are set forth. Moreover, they are set forth in connection with a description of Fig. 12 as mentioned in the first two lines of that page. A convenience copy of page 11 is enclosed. Withdrawal of the objection is respectfully requested.

Claims 1 – 10, 13 – 17 and 23 – 28 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Applicants note the Examiner's helpful comments with respect to Claim 1, step e), and Claims 4 and 23. Claim 1 has been amended to recite the step of adding a marker agent to label the contaminating microbes. Claims 4 and 23 have been amended to remove reference to the TWEEN and TRITON trademarks. Withdrawal of the rejection based on §112 is respectfully requested.

Claims 1 – 5, 8 – 10, 14 – 16 and 23 – 28 stand rejected under 35 U.S.C. §103 over the combination of Schrenk with Doshi. The Applicants note with appreciation the Examiner's detailed comments applying both references against those rejected claims. Nonetheless, the Applicants respectfully submit that, even if one skilled in the art were to make the hypothetical combination, the

resulting methodology would still fail to teach or suggest the subject matter of the rejected claims.

The Applicants first note that Doshi discloses a process wherein blood is agglutinated at the same time that the red blood cells are separated/filtered from an absorbent pad that contains an agglutinating agent. This is contrasted to the rejected claims which first subject a sample of a blood product to an aggregation treatment and then, after the aggregation treatment, passes the sample over a first filter.

There is the further difference that Doshi does not disclose selectively lysing residual cells of the filtrate.

There is a still a further difference. Although it is readily seen that Doshi discloses a second filter (and even a third filter in some instances), such a second filter is intended to "trap any extra red blood cells that may escape from the absorbent pad." This may be seen, for example, at the top of Column 12. Thus, the secondary filter of Doshi collects residual red blood cells and allows the remaining material to flow through the secondary filter. The materials flowing through the secondary filter would include any contaminating microbes.

This is sharply contrasted to the rejected claims inasmuch as the Applicants actually recover the contaminating microbes by passage of filtrate over the second filter but allowing passage of the cellular debris. In other words, the Applicants' second filter operates in the opposite way of the Doshi filters. Said differently, the Doshi filters collect red blood cells and allow the remaining filtrate including contaminating microbes to pass through while the Applicants' second filter recovers the contaminating microbes and allows the remaining materials, including cellular debris, to pass through the filter.

There is yet a further difference inasmuch as the Applicants' rejected Claim 1 recites analyzing material on the second filter to detect labeled contaminating microbes possibly retained by the

second filter. Inasmuch as Doshi fails to disclose retaining the contaminating microbes on the second filter, Doshi inherently fails to disclose analyzing the material on the second filter to detect labeled contaminating microbes possibly retained by the second filter.

In any event, the rejection acknowledges that Doshi fails to selectively lyse the residuals cells. The rejection therefore turns to Schrenk to provide such teachings. Schrenk indeed discloses treatment of an entire blood sample in a chamber with a reagent which causes lysis of red and white blood cells. Such lysis produces a concentrate of fluid components of blood, cellular debris and microorganisms. The concentrate is then withdrawn from the chamber.

The rejection states that it would be obvious to insert the Schrenk lysis step into the Doshi process subsequent to the agglutination/filter step with the absorbent pad of Doshi. The problem is that Schrenk does not provide any teachings or suggestions to make such a combination and, in any event, there are no teachings or suggestions to make a combination at the point in the claimed process as specified in the rejection.

Schrenk is essentially a self-contained sample collector which treats untreated blood. Therefore, if one skilled in the art were tempted to make a combination of Schrenk with Doshi, such an attempt would likely be made at the front end of the process and not in the middle of the process. There are also no teachings or suggestions in Doshi that would lead one skilled in the art to pluck the lysis aspect of Schrenk and insert it into the middle of the Doshi process. Thus, the Applicants respectfully submit that one skilled in the art would have no real motivation to make the combination.

In any event, the Applicants respectfully submit, that even if the combination were to be made, the resulting method would still fail to teach or suggest the subject matter of the rejected claims. In particular, even if the lysis step were inserted as suggested in the rejection, the method

would still begin with the step of applying a blood product to an absorbent pad impregnated with an agglutination reagent. This is different from the Applicants' rejected claims, which recite subjecting a sample of the blood product to an aggregation treatment, followed by filtering.

Of greater importance, however, is the complete opposite approach of the combined Doshi/ Schrenk method, which would recover lysed blood cells on the second filter and allow microorganisms to pass through the second filter. This would be in sharp contrast to the Applicants' claims, which recover the contaminated microbes from the lysate on the second filter, but allow passage of the cellular debris, which would include the lysed blood cells. The Applicants respectfully submit that these opposite teachings with respect to the second filtering step are compelling evidence of patentability over both of the Doshi and Schrenk references, whether taken individually or collectively. Doshi teaches a second filtering step that allows the microorganisms to pass through the second filter, while the Applicants retain the contaminating microbes on the second filter and allow the other materials to pass by.

As a consequence of the opposite approach discussed above, a combined Doshi/Schrenk method would also fail to teach or suggest the Applicants' claimed step of analyzing material on the second filter to detect labeled contaminating microbes possibly retained by the second filter. Inasmuch as the Doshi disclosure does not retain the microorganisms on the second filter, it inherently cannot analyze material on the second filter to detect labeled contaminating microbes retained by the second filter. Withdrawal of the rejection of Claims 1 – 5, 8, 10 and 14 – 16 and 23 – 28 is respectfully requested.

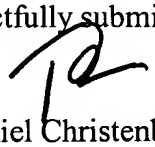
Claims 6 and 7 stand rejected under 35 U.S.C. §103 over the further combination of Cathey with Schrenk and Doshi. The Applicants have already established that a combination of Schrenk with Doshi fails to teach or suggest the subject matter of Claims 1 – 5, 8, 10, 14 – 16 and 23 – 28.

Further hypothetically combining Cathey with the primary and secondary references would fail to cure the deficiencies set forth above. Therefore, the Applicants respectfully submit that Claims 6 and 7 are patentable over that combination. Withdrawal of the rejection is respectfully requested.

Claims 9 and 13 stand rejected under 35 U.S.C. §103 over the further combination of Besson-Faure with Schrenk and Doshi. The Applicants have already established that a combination of Schrenk with Doshi fails to teach or suggest the subject matter of Claims 1 – 5, 8, 10, 14 – 16 and 23 – 28. Further hypothetically combining Besson-Faure with the primary and secondary references would fail to cure the deficiencies set forth above. Therefore, the Applicants respectfully submit that Claims 9 and 13 are patentable over that combination. Withdrawal of the rejection is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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[0032] This invention also provides a device for concentrating and labeling contaminating microbes possibly present in a blood product comprising, as shown in Fig. 12:

a first watertight, sterile tank (1) containing at least one blood cell aggregation agent and possibly at least one agent for labeling pathogenic microbes;

a second watertight, sterile tank (2) containing at least one lysis agent for blood cells and possibly at least one agent for labeling pathogenic microbes;

a first filter (3) placed between the first and second tanks and capable of retaining the aggregates formed in the first tank;

a second filter (4) placed downstream of the second tank and capable of retaining the possible contaminating pathogenic microbes; and

watertight, sterile connector (5) placed between the first tank (1) and the first filter (3), between the first filter (3) and the second tank (2), and between the second tank (2) and the second filter (4).

[0033] According to a preferred embodiment, the device comprises a watertight, sterile connector (6) to connect the bag containing the blood product to the first sterile tank (1). The watertight, sterile connection (6) connecting the bag containing the blood product to the first sterile tank is advantageously equipped with a reverse lock valve (7).

[0034] According to another preferred embodiment, the device comprises a sampling device to sample a determined volume of the blood product directly from a storage bag of the product into the first tank (1).

[0035] The first watertight, sterile tank (1) is advantageously fitted with a sample suctioning system (8). The suctioning system is preferably a piston. According to another preferred embodiment, the second filter (4) is enclosed in a membrane support composed of two parts that can be separated for removing the filter. The device i advantageously enclosed and sterile.